# [COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE ON HEALTH ON JUNE 19, 2007]

110TH CONGRESS
1ST SESSION

# H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the medical device user fee provisions, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the medical device user fee provisions, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; REFERENCES IN ACT.**

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device User Fee Amendments of 2007''.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other

provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act.

# TITLE I—FEES RELATED TO MEDICAL DEVICES

**SEC. 101. DEFINITIONS.**

Section 737 (21 U.S.C. 379i) is amended—

(1) in paragraph (4)—

(A) in subparagraph (A), by striking ''or an efficacy supplement,'' and inserting ''an efficacy supplement, or a 30-day notice,''; and

(B) by adding after subparagraph (E) the following:

''(F) The term '30-day notice' means a supplement to an approved premarket application or premarket report under section 515 that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.'';

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (7), (8), (9), and (11), respectively;

(3) by inserting after paragraph (4), as amended by paragraph (1) of this section, the following:

''(5) The term 'request for classification information' means a request made under section 513(g)

for information respecting the class in which a device has been classified or the requirements applicable to a device.

''(6) The term 'annual fee', with respect to periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a PMA approval order (as described in section 814.82(a)(7) of title 21, Code of Federal Regulations (or any successor regulation)).'';

(4) in paragraph (9), as so redesignated—

(A) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(B) by striking ''April 2002'' and inserting ''October 2001'';

(5) by inserting after paragraph (9), as so amended, the following:

''(10) The term 'person' includes an affiliate thereof.''; and

(6) by inserting after paragraph (11), as redesignated under paragraph (2) of this section, the following:

''(12) The term 'establishment subject to registration' means an establishment that is required to

register with the Secretary under section 510 and is one of the following types of establishments:

''(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, as defined in section 201(h), including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

''(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that performs manufacturing operations on a single-use device.

''(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.''.

**SEC. 102. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 738(a)(2) (21 U.S.C. 379j(a)(2)) is amended—

(A) by amending the paragraph heading to read as follows:

''(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—''.

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking ''a fee equal to the fee that applies'' and inserting ''a fee equal to 75 percent of the fee that applies'';

(B) in clause (iv), by striking ''21.5 percent'' and inserting ''15 percent'';

(C) in clause (v), by striking ''7.2 percent'' and inserting ''7 percent'';

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v), as amended under this paragraph, the following:

''(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).'';

(F) in clause (viii), as so redesignated, by striking ''1.42 percent'' and inserting ''1.84 percent''; and

(G) by inserting after such clause (viii) the following:

"(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

"(x) For periodic reporting concerning a class III device, the annual fee shall be equal to 3.5 percent of the fee that applies under clause (i).".

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

"(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(3) shall pay such fees upon submission of the first portion of such applications.".

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended by adding after clause (iii) the following:

''(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for a modular application submitted under section 515(c)(4) that is withdrawn before a second module is submitted and before a first action on the first module. If the modular application is withdrawn after a second or subsequent module is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the modules submitted.''.

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

''(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to registration shall be subject to a fee for each initial or annual registration under section 510

beginning with its registration for fiscal year 2008.

"(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

"(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.".

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the following fee amounts:

| Fee Type | Fiscal Year 2008 | Fiscal Year 2009 | Fiscal Year 2010 | Fiscal Year 2011 | Fiscal Year 2012 |
|---|---|---|---|---|---|
| Premarket Application ..... | $185,000 | $200,725 | $217,787 | $236,298 | $256,384 |

| Fee Type | Fiscal Year 2008 | Fiscal Year 2009 | Fiscal Year 2010 | Fiscal Year 2011 | Fiscal Year 2012 |
|---|---|---|---|---|---|
| Establishment Registration .... | $1,706 | $1,851 | $2,008 | $2,179 | $2,364". |

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking "Annual Fee Setting" and inserting "ANNUAL FEE SETTING"; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended under paragraph (1), is further amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(B) by inserting after paragraph (1) the following:

"(2) ADJUSTMENT.—

"(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of estab-

lishments submitting fees for fiscal year 2009 is less than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is less than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

''(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.''; and

(C) in paragraph (4), as redesignated under this paragraph, in subparagraph (A)—

(i) by striking ''For fiscal years 2006 and 2007, the Secretary'' and inserting ''The Secretary''; and

(ii) by striking ''for the first month of fiscal year 2008'' and inserting ''for the first month of the next fiscal year''.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking '', partners, and parent firms''; and

(B) by striking ''clauses (i) through (vi) of subsection (a)(2)(A)'' and inserting ''clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)''.

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking '', partners, and parent firms''.

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking ''(B) EVIDENCE OF QUALIFICATION.—An applicant'' and inserting the following:

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant'';

(ii) by striking ''The applicant shall support its claim'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim'';

(iii) by striking ''partners, and parent firms'' each place it appears; and

(iv) by striking the last sentence and inserting ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(ii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate

that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts and sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts and sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

''(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

''(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement (other than a 30-day notice), or periodic reporting concerning a class III device; and

''(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.''.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking ''2004'' and inserting ''2008''; and

(B) by striking ''(a)(2)(A)(vii)'' and inserting ''(a)(2)(A)(viii)''.

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A)(1) (21 U.S.C. 379j(e)(2)(A)(1)) is amended by striking ", partners, and parent firms".

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(A)) is amended—

(i) by striking "(B) EVIDENCE OF QUALIFICATION.—An applicant" and inserting the following:

"(B) EVIDENCE OF QUALIFICATION.—

"(i) IN GENERAL.—An applicant";

(ii) by striking "The applicant shall support its claim" and inserting the following:

"(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim";

(iii) by striking ", partners, and parent firms" each place it appears;

(iv) by striking the last sentence and inserting "If no tax forms are submitted

for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(ii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts and sales for the most recent year in both the local currency of such country and in United States dollars, the

exchange rate used in converting such local currency to dollars, and the dates during which these receipts and sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

''(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).''.

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day no-

tice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsection (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

''(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to registration shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.''.

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(D)—

(A) in the matter preceding clause (i), by striking ''For fiscal year 2007'' and inserting ''For fiscal year 2007 and for each subsequent year'';

(B) in clause (i), by striking ''applicable to fiscal year 2007'' and inserting ''applicable to such fiscal year''; and

(C) in clause (ii)—

(i) by striking ''subparagraph (C)'' and inserting ''this subparagraph''; and

(ii) by striking ''for fiscal year 2006'' and inserting ''for the previous fiscal year''; and

(2) by amending paragraph (2) to read as follows:

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.''.

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $48,431,000 for fiscal year 2008;

"(B) $52,547,000 for fiscal year 2009;

"(C) $57,014,000 for fiscal year 2010;

"(D) $61,860,000 for fiscal year 2011; and

"(E) $67,118,000 for fiscal year 2012.".

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount

of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

**SEC. 103. ANNUAL REPORTS.**

Beginning with fiscal year 2008, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report concerning—

(1) the progress of the Food and Drug Administration in achieving the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record during such fiscal year, and the future plans of the Food and Drug Administration for meeting the goals, not later than 60 days after the end of each fiscal year during which fees are collected under part 3 of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.); and

(2) the implementation of the authority for such fees during such fiscal year, and the use, by the Food and Drug Administration, of the fees col-

lected during such fiscal year (including a description of the use of such fees for postmarket safety activities), not later than 120 days after the end of each fiscal year during which fees are collected under the medical device user-fee program reauthorized by this Act.

**SEC. 104. CONSULTATION.**

(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2012, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i, 379j), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry and patient and consumer advocacy groups; shall present

such recommendations to the congressional committees specified in such subsection; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.

**SEC. 105. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.**

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose, $7,100,000 for fiscal year 2008, and for each of the fiscal years 2009 through 2012, $7,100,000 increased by the amount necessary to offset the effects of inflation occurring after October 1, 2007.

**SEC. 106. EFFECTIVE DATE.**

The amendments made by this title shall take effect on the date of the enactment of this title, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2007, regardless of the date of enactment.

**SEC. 107. SUNSET CLAUSE.**

The amendments made by this title cease to be effective October 1, 2012, except that section 103 (regarding annual reports) ceases to be effective January 31, 2013.

# TITLE II—AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES

**SEC. 201. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.**

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2007'' and inserting ''2012''.

**SEC. 202. REGISTRATION.**

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking ''On or before'' and inserting ''(1) On or before'';

(2) by striking ''or a device or devices''; and

(3) by adding at the end the following:

''(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.''.

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by striking ''On or before December 31'' and all that follows and inserting the following: ''Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

''(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

''(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

''(ii) with respect to devices, register with the Secretary during the period beginning on

October 1 and ending on December 31 of each year.''.

**SEC. 203. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.**

Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended, in the matter preceding subparagraph (A), by striking ''Each person'' and all that follows through ''the following information:'' and inserting ''Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:''.

**SEC. 204. ELECTRONIC REGISTRATION AND LISTING.**

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

''(p)(1) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

''(2) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.''.

**SEC. 205. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.**

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.